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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/551,188	04/17/2000	Axel Ullrich	7683-165	1301

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FOLEY & LARDNER
WASHINGTON HARBOUR
3000 K STREET, N.W.
SUITE 500
WASHINGTON, DC 20007-5109

EXAMINER
O HARA, EILEEN B

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 10/21/2002 21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/551,188	ULLRICH ET AL.	
	Examiner	Art Unit	
	Eileen B. O'Hara	1646	

-- The MAILING DATE of this communication appears n the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17,21,25,30 and 75-77* is/are pending in the application.

4a) Of the above claim(s) *17, 21 and 25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30 and 75-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *17,21,25,30 and 75-77* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Claims 17, 21, 25, 30 and 75-77 are pending in the instant application. Claim 30 has been amended and claims 75-77 have been added as requested by Applicant in Paper Number 19, filed August 8, 2002.

Claims 17, 21 and 25 are withdrawn as being drawn to a non-elected invention.

Claims 30 and 75-77 are currently under examination.

Priority

2. Applicants' amendment to the specification to update the priority document is acknowledged.

Withdrawn Objections to Specification

3. The objections to the specification are withdrawn in view of Applicants' amendment, except for the objection to the specification for page 11, line 3, in which the word "with" should be deleted. Although Applicants on page 4 of the amendment state that the word "with" has been deleted, there was no amendment directing this change.

Withdrawn Rejections

4. The rejection of claim 30 under 112 § 2 is withdrawn in view of Applicants' amendment.

Specification

5. The disclosure is objected to because of the following informalities: on page 47, section 6.2.4. refers to experiments in which MCK-10 is overexpressed, and phosphorylation and glycosylation is assayed. These experiments are referred to in Figure 4A, however, these experiments were actually demonstrated in Fig. 6A.

Appropriate correction is required.

Claim Rejections - 35 USC § 101 and § 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 30 and 75-77 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. Claims 30 and 75-77 are directed to a method of modulating the endogenous enzymatic activity of the tyrosine kinase MCK-10 receptor comprising the amino acid sequence of SEQ ID NO: 2 or splice variants thereof or a receptor 80% homologous to that receptor, in a mammal, comprising administering to the mammal an effective amount of a ligand to the MCK-10 receptor protein to

modulate the enzymatic activity. Claim 30 was previously rejected under § 112, first paragraph, however upon further consideration, claim 30 and 75-77 are also rejected under 35 USC § 101, as not having any specific and substantial utility, or a well established utility, as determined according to the current Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday, January 5, 2001.

The reasons for the enablement rejection were discussed in the previous Office Action, Paper No. 17, at pages 3-5. Applicants traverse the rejection and assert that the specification teaches various ligands that may bind to an MCK-10 receptor, and teach how the skilled artisan may identify and isolated such ligands. Applicants also teach that an antibody is a ligand, that the specification teaches how to generate MCK-10-specific antibodies, and also disclose antisera generated against certain MCK-10 epitopes. Applicants also assert that the Examiner errs in stating that the applicant teaches "no assay" to determine if a potential ligand administered to a mammal "actually modulated the activity of the receptor", and support this with teachings at section 6.2.4 at page 47, in which the MCK-10 DNA is expressed in 293 cells and the ability of the MCK-10 receptor to phosphorylate tyrosine is measured. Applicants also assert that the specification makes clear that modulation of MCK-10 receptor is desirable, *inter alia* because modulation via ligands can be useful in treating diseases such as cancer.

Applicants' arguments have been fully considered but are not deemed persuasive. Although the specification discloses a method of assaying for compounds (antibodies) that can bind to and possibly modulate the activity of the MCK-10 receptor, the claims are directed to a method of modulating the endogenous activity of the receptor in a mammal, and it is not known from the prior art or disclosed in the specification what the effect would be of "modulating" this

receptor in a mammal. The endogenous ligand(s) is not known, nor are the molecules in the phosporylation pathway that would be activated or inhibited by modulation of this receptor. Even if an antibody were identified by the *in vitro* assay described in the specification that either activated or inhibited the MCK-10 receptor, the method of administering the antibody would have no utility, because it is not known what the effect would be on the mammal, since the downstream effects of the receptor's activity are not known. Applicants assert that that the specification makes clear that modulation of MCK-10 receptor is desirable, because modulation via ligands can be useful in treating diseases such as cancer. However, although the MCK-10 gene is expressed in several tumor cells, there is no evidence that modulation of this receptor would be useful in treating cancer. Administration of a ligand could possibly stimulate growth of cancer cells instead of inhibiting growth. Therefore, this method does not have a specific or substantial utility. The use of MCK-10 receptor requires further research to discover what the activities and biological significance of the protein is, if the receptor is involved directly or indirectly in any cancer, and whether either activation or inhibition of the receptor could be therapeutically advantageous for cancer treatment. It is possible that after further characterization, this protein might be found to be directly involved in abnormal cell proliferation, and that modulation of the receptor would be therapeutic. This further characterization, however, is part of the act of invention, and until it has been undertaken the Applicants' claimed invention is incomplete. Because the method has no specific and substantial utility, credibility cannot be assessed.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7.1 Claims 30 and 75-77 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

7.2 Claims 30 and 76 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification describes a method of modulating the endogenous enzymatic activity of the tyrosine kinase MCK-10 receptor comprising the amino acid sequence of SEQ ID NO: 2 or splice variants thereof or a receptor 80% homologous to that receptor, in a mammal, comprising administering to the mammal an effective amount of a ligand to the MCK-10 receptor protein to modulate the enzymatic activity. The instant specification describes antibodies that bind to the MCK-10 receptor, and therefore there is adequate written description for ligands that are antibodies or antibody fragments or derivatives. However, no other ligand has been described in the specification. Given that the receptor is an endogenous, naturally occurring receptor, there must be at least one natural ligand – however, none has been disclosed. The instant disclosure of only one type of ligand does not adequately support the scope of the claimed genus, which encompasses a substantial variety of subgenera. A genus claim may be supported by a representative number of species as set forth in *Regents of the*

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Lilly & Co, 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), which states:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention". Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1980) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.") Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d 1565, 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id at 1170, 25 USPQ2d at 1606."

A description of a genus of ligands may be achieved by means of a recitation of a representative number of ligands, defined by sequence or structure, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. The instant specification discloses, however, only one type of ligand, antibodies. Although the specification describes methods of identifying ligands, only one type has been adequately described. Therefore, it cannot be established that a representative number of species have been disclosed to support the genus claim.

It is believed that all pertinent arguments have been answered.

Conclusion

8. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner

Lorraine Spector 10/20/02

LORRAINE SPECTOR
PRIMARY EXAMINER